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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/205,251	12/04/1998	IRVING K. ARENBERG	INTRUS-4	8010
31498	7590	09/27/2004	EXAMINER	
DURECT CORPORATION 10240 BUBB ROAD CUPERTINO, CA 95014			THANH, LOAN H	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/205,251

Applicant(s)

ARENBERG ET AL.

Examiner

LoAn H. Thanh

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,26-29,48-60 and 63-82 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,26-29,48-59 and 63-82 is/are rejected.
- 7) ☒ Claim(s) 60 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Response to Amendment***

The rejection under 35 USC 112, 1<sup>st</sup> paragraph has been withdrawn in view of the amendment filed.

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the multiphased composite drug delivery unit (claim 60), the impermeable backing membrane , rate limiting center membrane and basement membrane comprising a bioadhesive material ( claim 61) and the two layered structure of the hydroxypropyl cellulose bioadhesive layer and lactose based non-adhesive baking layer ( claim 62) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

Claim 61 is objected to because of the following informalities: Double punctuation at the end of the sentence. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

Claim 50, 60-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The range of "at least 24 hours " is not disclosed in the specification as now claimed. Further the scope of at least 24 hours encompasses time which could be beyond months which is not disclosed in the specification. The subject matter of claims 60-63 lacks disclosure.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 26-29, 48-53, 63-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manning et al. (WO 97/38698)

Manning et al. disclose the invention substantially as claimed. Manning et al. disclose a drug delivery unit comprised of a biocompatible, biodegradable polymer support and at least one pharmacologically active agent that is placed such that it substantially contacts the round membrane of the middle ear. See page 4, lines 11-14,

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page 5, lines 9, page 6, lines 24-30. This would encompass the being in direct contact or against and "at least partially in said round window niche". With respect to the location of the drug delivery unit, it is disclosed on page 1, lines 19-21 that "access to the inner ear tissue regions is typically through a variety of structures including the round window membrane "... etc. That would narrow it to the location between the tympanic membrane and the round window that is the location of the round window niche since it is also disclosed that the drug delivery unit is in contact with the round membrane of the middle ear. Manning et al. teach that the device provides extended release. See page 4, lines 5-20 and abstract. On page 7, lines 7-12. Manning disclose the drug concentration can be varied over broad limits and is chosen depending upon solubility , pharmacological activity, desirable effect of the end product , patient size and weight all factors know to those skilled in the art. As for the language of the "the biocompatible polymer" it is well known in the art that that would be a synthetic as opposed to a "biopolymer" which is naturally occurring. With respect to the quantity of agent to be 10-40 wt % , Manning teaches the unit to be 0.05 to 4% wt and higher. See page 3, lines 8-15, page 4, lines 1-30, page 5, lines 8-23, page 7, lines 7-15, page 8, lines 8-15 and see claims 1-22. However, Manning does not disclose the specific volume of the drug delivery unit being 0.1 mm<sup>3</sup> and 250 mm<sup>3</sup> or any of the other limitations of the length and diameter of the unit. Manning teaches the drug delivery unit to be delivered into the middle and inner ear. It would have been obvious to one of ordinary skill in the art that the device of Manning would encompass such a broadly claimed range of the volume although he does not disclose the volume specifics of his

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device. Thus, it would have been obvious to one of ordinary skill in the art to modify the volume size as claimed as a mere design choice lacking any criticality of size as being merely preferable for the intended target ( ear) area depending on the size of the ear of the patient where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. With respect to the agent in nanogram to microgram quantities or the timing of the release of the agent , Manning teaches the dose to be preferably between 5-360 mg. However, Manning also teaches that those skilled in the art can determine optimal doses and dosage schedules. It would have obvious to one of ordinary skill in the art at the time the invention was made to modify the dosage or dosage schedules to one which is desired for the patient taking into consideration the parameters of the patient such as size , weight , severity of the condition of the disease in order to deliver therapeutically effective levels of drug to the patient that is prompt, prolonged , effective and safe.

Claims 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manning et al. (WO 97/38698) in view of Peterson (U.S. Patent No.4,472,394).

Manning et al. teaches the invention as substantially claimed. See above. However, Manning can be further supported by varying the time release of the agent by the teachings of Peterson. Peterson teaches implanting a pellet/ ruminant beneath the ear for extended controlled release of the active ingredient over a period of 60 days to 210 days. It would have been obvious to one of ordinary skill in the art at the time the

invention was made to modify the period of release of the drug of Manning et al. with a period of greater than a month as taught by Peterson in order to provide uniform extended release depending on the parameters (such as weight of patient, type of drug, solubility of drug, etc.) required for a dosing regiment. Further lacking any criticality or unexpected results, it would have been obvious to modify the time period since slow release and controlled release is well known in the medical arts when treating the patients with respect to severity of the disease and patient's medical history.

Claims 54-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manning et al. (WO 97/38698).

Manning teaches the invention as substantially claimed. See above. Manning specifically teaches a biocompatible polymer. However, Manning does not teach the material to be polyanhydride material, polyorthoester material, hydroxypropylmethyl cellulose, hydroxyethyl cellulose, hydrophilic microsphere or bioadhesive material. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the polymer material as a mere design choice to which the polymer is more available for use, cheaper, etc. for those skilled in the art. The material is not critical to the invention unless the material is some newly discovered material.

### ***Response to Arguments***

Applicant's arguments filed 11/18/03 have been fully considered but they are not persuasive. Applicant has addressed the rejection as now amended. It is not persuasive

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since the teaching of modify the quantities is taught by Manning and further, it is well known to one of ordinary skill in the art that parameters such as dosing and dosing schedules are modified to effectively treat the patient.

Peterson teaches that the dosing schedule is varied from days to months.

Applicant's arguments are not convincing that Peterson does not suggest the limitations of the claimed invention as a combination.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is




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(703) 305-0038. The examiner can normally be reached on Mon-Fri ( first Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
LoAn H. Thanh  
Primary Examiner  
Art Unit 3763

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